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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Lead Case No.: 3:21-cv-03825-AMO-LB **REPLY IN SUPPORT OF MOTION OF INTUITIVE SURGICAL, INC. TO EXCLUDE TESTIMONY OF KIMBERLY TRAUTMAN** Hearing To Be Renoticed Hearing Place: Courtroom 10 Judge: The Honorable Araceli Martínez-Olguín

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I. INTRODUCTION

In its motion to exclude the testimony of plaintiffs' "FDA" expert, Kimberly Trautman (Dkt. No. 123) ("Mot."), Intuitive demonstrated that Trautman's opinions that modifying a used EndoWrist to circumvent its use counter does not require FDA clearance because such activity (a) is not "remanufacturing" and (b) is not introducing a product into "commercial distribution," are inadmissible legal opinions and unreliable because they ignore virtually all of the pertinent evidence. Mot. at 7-15. Intuitive also demonstrated that Trautman's opinions fall outside the areas in which she has actual experience and expert knowledge. *See id.* at 8-9. Plaintiffs' opposition (Dkt. No. 161) ("Opp.") does not contravene Intuitive's showing.

Plaintiffs' attempt to characterize Trautman's opinions as something other than legal opinions is unavailing. And their argument that she should be allowed to testify to those legal opinions because they do not go to an ultimate issue in the case misstates both the law governing expert testimony and, more significantly, the antitrust laws applicable to plaintiffs' claims that make FDA clearance a central issue of law in this case.

Plaintiffs also fail to meet their burden to show that Trautman's opinions are reliable under the *Daubert* standards. Plaintiffs do not dispute that she focuses on the interpretation and application of FDA regulations – indeed, in their effort to avoid preclusion of this testimony as legal opinion, plaintiffs try to remake Trautman's opinion as one concerning how FDA "will interpret and enforce those regulations." Opp. at 11. Yet plaintiffs do not explain Trautman's failure to address the numerous and consistent statements *from FDA* interpreting those regulations and telling entities to cease their activities that flatly contradict her opinion. Instead, plaintiffs beg the Court to find that this challenge to Trautman's opinions goes to the weight of her testimony rather than its admissibility. But Trautman has not even offered the minimal degree of reliability required to survive *Daubert* scrutiny.

As for the question of Trautman's qualifications, plaintiffs simply argue that Trautman's role as a drafter of the Quality System Regulation ("QSR") is sufficient. But there is no dispute as to how that regulation defines "remanufacturing," and plaintiffs have no answer to the fact that Trautman lacks

experience in, or even exposure to, agency activity *applying* that definition. Trautman's experience on *different* issues does not qualify her to opine on the issues presented here.

II. ARGUMENT

Plaintiffs have not met their burden to establish the admissibility of Trautman's opinions. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993). Plaintiffs cannot demonstrate that she is not applying "agency law to the facts of [the] case" or describing the "parties' legal rights, duties and obligations under the law." *Nationwide Transp. Fin. v. Cass Info. Sys., Inc.*, 523 F.3d 1051, 1058 (9th Cir. 2008). Nor have Plaintiffs shown that her opinions are based on a complete review of the record, including a serious evaluation of the evidence that is most on point, as opposed to odds and ends derived from "plaintiff-curated records," *Smith v. Ill. Dep't of Transp.*, 936 F.3d 554, 558-59 (7th Cir. 2019), that ignore "the great weight of the evidence that contradicts [her] conclusion," *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176-77 (N.D. Cal. 2007). And Trautman's qualifications to offer an opinion on one subject do not qualify her to opine on others. *Rogers v. Raymark Indus., Inc.*, 922 F.2d 1426, 1431 (9th Cir. 1991).

A. Trautman Offers Inadmissible Legal Opinions.

Trautman's opinions that the modification of hospitals' EndoWrists by third parties to extend their number of uses does not satisfy the regulatory definitions of "remanufacturing" and "commercial distribution" violate the principle that experts may not testify on issues of law. *See* Mot. at 7-8. Plaintiffs' efforts to defend these opinions fail.

1. Trautman's Opinions Go Well Beyond "Referring" To the Law.

Plaintiffs' principal argument – that Trautman is simply "referring" to the law but is not offering opinions on the "ultimate issue of law" (Opp.at 6) – fails on both factual and legal grounds. The actual opinions set out in Trautman's report belie plaintiffs' characterization. For example, she writes:

- "Counsel for the Hospital Plaintiffs has asked me to evaluate whether such third-part[ies] … faced any FDA regulatory bar when engaging in the business of repairing EndoWrists…." Lazerow Dec. Ex. 1 (Dkt. No. 123.2) ¶ 6;

- "a 510(k) application is not required for [a third party] to extend the life of EndoWrist instruments, nor is compliance with the Quality System regulation 21 CFR § 820 or other FDA regulations such as Registration and Listing, Adverse Event Reporting,

> etc., because, in my opinion, just extending the life of the EndoWrist instruments does not meet the definition of 'remanufacturer,' as defined in 21 CFR § 820.3(w)[.]" *Id.* ¶ 82;
>
> - Third parties "that do not meet the definition of 'Manufacturer' per 21 CFR § 820.3(o) or 'Remanufacturer' per 21 CFR § 820.3(w) and do not perform the 'actions' outlined in one of the four categories described [in the Food Drug & Cosmetic Act ('FDCA') and the 510(k) regulation (21 C.F.R. § 807)] are not required to submit a 510(k) or other market application to the FDA." *Id.* ¶ 29;
>
> - "a 510(k) authorization is not required when: devices are not introduced into commercial distribution … or an entity does not significantly change a device's performance or safety specifications, or its intended use per the definition of remanufacturer in 21 CFR § 820.3(w)." *Id.*

Plaintiffs simply ignore these statements in her opening report, and the snippets they cite from her rebuttal report only further confirm that the core of her proposed testimony consists of legal opinions. *See, e.g.*, Opp. at 8 ("Trautman will explain that there are two prerequisites that must be satisfied for 510(k) clearance to be required: an IRC must 'both a) satisfy the regulatory definition of 'remanufacturer,' and b) place the medical devices at issue in 'commercial distribution.'").

Plaintiffs' argument that Trautman's opinions are admissible because the requirement for 510(k) clearance is "not an element of any of Plaintiffs' claims" or "an affirmative defense" (Opp. at 7) fails on multiple grounds. To begin with, the bar on expert testimony is not limited to "elements" of a claim or defense. Absent special circumstances not applicable here (such as when the content of the law of a foreign country is at issue), testimony *about the law* – especially about a question of U.S. law on which the federal courts are the ultimate authority – is virtually always precluded. *See In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d 61, 64-65 (S.D.N.Y. 2001) ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law.") (collecting cases).

In any event, plaintiffs grudgingly acknowledge that Trautman's legal opinions relate to an element of plaintiffs' claims here – antitrust injury. Opp. at 7. If 510(k) clearance is required to modify an EndoWrist so that it can be used more times than its FDA-cleared use limit, then there was no competitor that could legally provide the "competition" plaintiffs claim should have existed, and

plaintiffs cannot demonstrate antitrust injury.[1] Regardless of whether legality is "formally an element of the antitrust inquiry," courts – including the Ninth Circuit – have held that a plaintiff cannot suffer an antitrust injury if the allegedly impaired competition is illegal. *PharmacyChecker.Com v. Nat'l Ass'n of Bds. of Pharmacy*, 2023 WL 2973038, at *13 (S.D.N.Y. Mar. 28, 2023); *PharmacyChecker.com, LLC v. Nat'l Ass'n of Bds. of Pharmacy*, 530 F. Supp. 3d 301, 328-30 (S.D.N.Y. 2021) (discussing cases "where the plaintiff's business is illegal or enables illegal behavior").[2]

PharmacyChecker is directly on point. The court there granted a motion to exclude an FDA expert who planned to testify that "drugs that comply with FDA's labeling and approval requirements can be and are legally imported whether commercially or by individuals for their own personal use" and "[d]rugs that comply with FDA's approval requirements except for labeling or packaging differences may be imported under FDA's drug labeling exemptions." 2023 WL 2973038 at *15-16, *19. The court rejected plaintiffs' argument that the expert was not testifying to the ultimate issue of whether the enterprise was "completely or almost completely geared toward facilitating illegality," and instead found that the expert's opinion usurped the court's role in determining "the purely legal question of whether personal importation is permissible under U.S. law" because it "directly state[s] what the law is as it relates to personal pharmaceutical importation." *Id.* at *16-17.[3] Like the FDA expert in *PharmacyChecker*, Trautman offers opinions that purport to "dictate what the law is." *Id.* at *17. That

[1] Plaintiffs cite no authority for their argument that the antitrust injury inquiry turns on whether FDA was "willing and able to seek and win injunctions" to stop third parties' unlawful remanufacturing. Opp. at 11 n.9. Courts have routinely rejected that argument because unlawful activity does not magically obtain lawful status simply because it is not prosecuted. *See, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 792 (8th Cir. 2006); *JEM Mktg., LLC v. Cellular Telecomms. Indus. Ass'n,* 308 N.J. Super. 160, 169 (N.J. Super. Ct. App. Div. 1998). In any event, there is no evidence that FDA was not "willing and able" to pursue an injunction. Rather, such action was unnecessary. FDA demanded that entities engaged in modifying EndoWrists cease those activities until and unless they obtained FDA clearance, and the entities ceased the activities. *See generally* Lazerow Dec. Exs. 11-15, 17 (Dkt. Nos. 123.12-.16, .18).

[2] *See also Modesto Irrig. Dist. v. Pac. Gas & Elec. Co.*, 309 F. Supp. 2d 1156, 1169-70 (N.D. Cal. 2004), *aff'd*, 158 F. App'x 807 (9th Cir. 2005); *Snake River Valley Elec. Ass'n v. PacifiCorp*, 357 F.3d 1042, 1050 n.8 (9th Cir. 2004); *Realnetworks, Inc. v. DVD Copy Control Ass'n, Inc.*, 2010 WL 145098, at *6 (N.D. Cal. Jan. 8, 2010).

[3] The *PharmacyChecker* court held as a matter of law that the "competition" the defendant allegedly prevented would have been unlawful, contrary to the opinion of the plaintiff's expert, and granted summary judgment for defendants based on the absence of antitrust injury. 2023 WL 2973038, at *30.

is the role of the Court, not an expert. *See Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004) ("[I]nstructing the jury as to the applicable law is the distinct and exclusive province of the court.").

The cases Plaintiffs cite (*see* Opp. at 6-7) do not support a different conclusion. None dealt with experts who, like Trautman, purported to interpret a statute or regulation or offered opinions about how the law should be applied. *Hangarter*, for example, considered opinions about whether the defendants comported with industry standards. 373 F.3d at 1015-16. The court permitted the testimony because the expert did not interpret the law but simply "relied in part on his understanding of the requirements of state law" – which were not directly at issue in the case. *Id.* at 1017. Plaintiffs argue that Trautman similarly relies on her understanding of the FDCA and the relevant regulations, but she goes well beyond that to offer legal conclusions about FDA regulations directly at issue in this case. Her discussion of the FDCA and FDA regulations is not a mere touchpoint for discussion of a separate question, such as industry standards; it is, rather, the core testimony she proposes to offer in this case.

King v. GEICO Indem. Co., 712 F. App'x 649 (9th Cir. 2017), and *Sumotext Corp. v. Zoove, Inc.*, 2020 WL 533006 (N.D. Cal. Feb. 3, 2020), also offer no support for plaintiffs. *King* dealt with an insurance industry expert who testified as to GEICO's handling of an insurance claim "in relation to industry standards and GEICO's own claim manual." 712 F. App'x at 651. Even though the manual incorporated the state statute under which the plaintiff filed her claims, the expert testified only to GEICO's conduct, not his interpretation of the statute. *Id.* *Sumotext* considered a motion *in limine* challenging an economist's use of the term "market power" in opining about alleged relevant markets. 2020 WL 533006, at *12. The court held that the economist could offer economic analysis using economic terms like "market power" that are also "used in antitrust jurisprudence" but do not "have so 'separate, distinct, and specialized' a meaning in the law as opposed to economics that its use rises to the level of a legal conclusion." *Id*. (quoting *United States v. Diaz*, 876 F.3d 1194, 1197 (9th Cir. 2017)) The Court further explained that "although an expert witness may express facts or opinions using 'legal terminology,' he *may not explain the law to the jury or tell the jury how to apply the law to the facts of*

the case." *Id.* (emphasis added) (citing *Nationwide*, 523 F.3d at 1058-59). That is exactly what plaintiffs want Trautman to do: interpret the regulations to opine on the legality of the conduct at issue.

The cases on which plaintiffs rely thus undercut, rather than support, their argument. Moreover, plaintiffs offer nothing to distinguish the recent on-point decisions of two courts that excluded the opinions of FDA experts regarding the definition of "remanufacturing" and the applicability of FDA regulations to the modification of EndoWrists – the very same conduct at issue here. Lazerow Dec. Exs. 9 and 10 (Dkt. Nos. 123.10-.11). Trautman's opinions are exactly what those courts warned against: ultimate legal opinions as to whether the third parties complied with FDA regulations, including opinions that seek to contradict FDA's own stated views. *See* Lazerow Dec. Ex. 9 at 8, 16. Plaintiffs' discussion of those decisions, tucked away in a footnote (Opp. at 11 n.9), seeks to distinguish them based on the fact that the plaintiffs in those cases were would-be *competitors* rather than would-be *customers* like plaintiffs here. This argument fails to recognize that it would have been just as unlawful for these hospitals to hire Rebotix to remanufacture their EndoWrists and then use them on patients as it would have been for Rebotix to provide that "service." *Cf. United States v. Kaplan*, 836 F.3d 1199, 1208-11 (9th Cir. 2016) (doctor who used medical devices on patients past their approved useful life acted unlawfully).[4]

In the end, Plaintiffs cannot dispute that "remanufacturing" and "commercial distribution" are terms with *legal* meanings in the context of the FDCA and FDA regulations. Trautman's views on how those terms should be interpreted and applied are inadmissible legal opinions.[5]

[4] In the same footnote, plaintiffs speculate that someone could have obtained FDA clearance to offer the remanufacturing option lawfully. Opp. at 11 n.9. But as explained in Intuitive's briefs on the parties' summary judgment motions, there is no evidence that Intuitive has ever interfered with any remanufacturer obtaining such clearance. In any event, this question has nothing to do with Trautman's testimony, which addresses whether remanufacturers that *lacked* FDA clearance (and, by extension, those that purchased the remanufacturing service from them) were acting unlawfully.

[5] Plaintiffs' attack on the opinions of Intuitive's FDA expert, Christy Foreman (Opp. at 10 & n.7), does not support a different result. Plaintiffs did not file a motion to exclude Ms. Foreman's opinions. And contrary to plaintiffs' assertion (*id.* at 10), Intuitive did not "acknowledge" that it intends to offer legal opinions from Ms. Foreman; rather, Intuitive made clear that Ms. Foreman will not testify about legal opinions if Ms. Trautman is precluded from doing so. Mot. at 7 n.2.

2. Trautman's Opinion Regarding "Commercial Distribution" Is Inadmissible for the Additional Reason That It Contradicts the Law.

The fact that Ninth Circuit precedent directly contradicts Trautman's opinion relating to the statutory term "commercial distribution" provides further evidence that Trautman offers inadmissible legal opinions. Trautman opines that the "commercial distribution" requirement in 21 C.F.R. § 807.81(a) precludes a finding that the activities at issue required FDA clearance. Lazerow Dec. Ex. 1 ¶¶ 29-30, Ex. 16 (Dkt. No. 123.17) ¶ 59. According to Trautman, the activities "do not meet the regulatory threshold of an entity placing a medical device into interstate commerce for commercial distribution" because such entities are not "taking ownership or becoming involved in the sale or resale of such serviced or refurbished device." Lazerow Dec. Ex. 16 ¶ 8(b). But the Ninth Circuit has already determined that the key term in the definition of "commercial distribution" on which Trautman hangs her opinion – "held or offered for sale," 21 CFR § 807.3(b) – is not limited to a "sale in the strict sense" but rather covers a "commercial actor in a commercial setting, using a commercial product" intended for use to treat patients. *Kaplan*, 836 F.3d at 1209-10.

Plaintiffs' admission that the language interpreted by the Ninth Circuit ("held for sale") "includes some overlap with the regulatory definition at issue here" ("held or offered for sale") (Opp. at 12, n.10), should end the inquiry because courts generally interpret a term appearing several places in a statute or regulatory scheme the same way each time it appears. *Ratzlaf v. United States*, 510 U.S. 135, 143 (1994); *see also Gustafson v. Alloyd Co.*, 513 U.S. 561, 570 (1995); *Wis. Dep't of Revenue v. William Wrigley, Jr., Co.*, 505 U.S. 214, 225 (1992). This rule is particularly applicable here, given that FDA derived its authority to promulgate 21 C.F.R. § 807 (which includes the definition of "commercial definition" applicable to the marketing of remanufactured devices) from the same statute at issue in *Kaplan* — 21 U.S.C. § 331. And plaintiffs get no help from the fact that the language interpreted by the Ninth Circuit ("held for sale") is *narrower* than the language at issue here ("held or offered for sale"). Requirements applicable when a device is "held *or offered* for sale" might have a broader application than those applicable when a device is merely "held for sale" – they would not have a more limited one.

Plaintiffs do not even try to distinguish the Ninth Circuit's observation in *Kaplan* that use of the devices for more uses than they were cleared for was "particularly critical to [its] decision" because

"[e]ven a physician can make a product dangerous for a patient if the product is utilized improperly." 836 F.3d at 1210. Nor do plaintiffs wrestle with the court's rejection of the argument that there was no sale because "title and possession of the guides were not transferred to patients," *id.* at 1209 – the exact argument Trautman offers here. Indeed, plaintiffs ignore this argument, even though Intuitive pointed out in its motion that the FDA long ago stopped making "ownership" a criteria for regulatory determinations. *Compare* Opp. at 11-13 *with* Mot. at 14 n.7. Ultimately, *Kaplan*'s emphasis on "the commercial nature of the transaction, actors, and products" to find a violation of the FDCA firmly applies here, where hospitals (commercial actors) would use these remanufactured devices on patients, who effectively pay for the cost of products used in the course of their treatment. *Kaplan*, 836 F.3d at 1209. Plaintiffs do not and cannot deny this.

B. Trautman's Opinions Are Unreliable.

Trautman's opinions on the definition of "remanufacturer" are unreliable because she ignored FDA's statements on the topic over the course of nearly a decade and instead relied on inapposite and/or unsubstantiated evidence that, in context, does not support her conclusions. Mot. at 9-13. The law is clear that "reliability is the lynchpin—the flexibility afforded to the gatekeeper goes to how to determine reliability, not whether to determine reliability." *United States v. Valencia-Lopez*, 971 F.3d 891, 898 (9th Cir. 2020); *see also id.* ("[A] district court abdicates its gatekeeping role, and necessarily abuses its discretion, when it makes no reliability findings.").

Plaintiffs do not offer any meaningful defense of the reliability of Trautman's opinions, instead resorting to the well-worn generic argument that Intuitive's challenges go to "the weight the jury should give her testimony, not its admissibility." Opp. at 14; *see also id.* at 6, 15. The Ninth Circuit has made clear that this facile dodge cannot be used to escape *Daubert* scrutiny when a meaningful reliability challenge has been offered. *See United States v. Holguin*, 51 F.4th 841, 855 (9th Cir. 2022) (a district court's conclusion that a challenge goes to "weight, not admissibility" is "not a reliability finding" (citing *Valencia-Lopez*, 971 F.3d at 899 ("Dismissing an argument as 'going to the weight, not admissibility, of [the expert's] testimony' is not a reliability determination.")). This is especially true where the expert's testimony rests on her claimed "experience," not a concrete scientific test or study.

See Valencia-Lopez, 971 F.3d at 898 ("[R]eliability becomes more, not less, important when the 'experience-based' expert opinion is perhaps not subject to routine testing, error rate, or peer review type analysis, like science-based expert testimony.").

To be clear, Intuitive is not criticizing Trautman for merely failing to "emphasize specific communications favored by Intuitive." Opp. at 13. This is not a situation in which some of FDA's statements offered one conclusion and others offered a different one, with Trautman supporting one over the other. To the contrary, there is not a single statement in the record from *anyone* at FDA expressing a view consistent with Trautman's opinions. Every statement from FDA addressing whether the activity at issue constitutes remanufacturing requiring 510(k) clearance has confirmed that it does. Intuitive has shown that Trautman's opinions are unreliable not simply because she ignored the "great weight of the evidence," *Smith*, 936 F.3d at 558-59 – Intuitive has shown that she has *ignored it all*. Instead, plaintiffs fed Trautman odds and ends from clearly inadmissible sources that they preferred, such as self-serving statements from interested third parties and the unsubstantiated report of a stock analyst.[6]

Plaintiffs cite communications from Rebotix and Intuitive *to* FDA (the latter on a different subject) and a single email from an FDA official stating that FDA's determination that Rebotix's activities constituted remanufacturing was not an *appealable* decision. Opp. at 13-14. None of these items provide a basis for an expert opinion on what the regulations mean; they certainly offer no support for any opinion on how FDA would enforce them. To the contrary, the undisputed record shows that FDA *rejected* Rebotix's arguments and demanded that Rebotix cease operations, which it did.[7] FDA also rejected Intuitive's interpretation of a different regulation and demanded that Intuitive obtain new FDA clearances, and Intuitive did so. Nothing in these chains of events supports Trautman's opinions;

[6] Plaintiffs have no credible answer for the *Rebotix* court decision excluding expert testimony from an FDA expert who relied on the Deutsche Bank report. Opp. at 15. Even if Trautman had done the work needed to conclude that the report was reliable (which she did not), a financial analyst report is plainly not a source an expert would rely upon in interpreting FDA regulations. *See* Lazerow Dec. Ex. 9 at 15.

[7] Plaintiffs have no answer for the fact that when FDA told Rebotix that its determination was not in an appealable form, the agency instructed Rebotix on how it could obtain an appealable order. *See* McCuaig Dec. Ex. 23 (Dkt. No. 161.24) at -5839. Rebotix chose not to do so. This communication certainly offers no *affirmative* support for Trautman's opinions.

there is certainly no basis to conclude that an expert in the field would rely on statements made *to* FDA and then ignore how FDA responded and what happened thereafter.

In short, plaintiffs' implicit argument that it is appropriate to "weigh" arguments that self-interested parties unsuccessfully made to FDA and a financial analyst report with undisclosed sourcing against the almost decade-long, unqualified statements from FDA on how and whether FDA regulatory requirements apply, is absurd on its face. Trautman's opinions fail the *Daubert* test.

C. Trautman Is Not Qualified To Offer the Opinions at Issue.

Even if Trautman's opinions about remanufacturing were not inadmissible and unreliable legal opinions, she still should not be permitted to testify to them because plaintiffs cannot demonstrate that she is qualified to opine on the application of the definition of "remanufacturing" to specific activities. The experience that plaintiffs tout – Trautman's role 30 years ago in authoring the QSR (of which the definition of remanufacturing is a tiny part) – does not qualify her to offer opinions about how FDA applies that regulation in practice. *Montera v. Premier Nutrition Corp.*, 2022 WL 1225031, at *9 (N.D. Cal. Apr. 26, 2022) ("A person qualified to give an opinion on one subject is not necessarily qualified to opine on others." (quoting *Rogers*, 922 F.2d at 1431)). There is no dispute between the parties arising from the drafting of the QSR or the words chosen to define remanufacturing. But Trautman's opinions address how the regulation is properly *applied*, and she has no experience with that.

Plaintiffs' reliance on *United States v. Pacific Gas & Electric*, 2016 WL 3268994 (N.D. Cal. June 15, 2016) (Opp. at 6), is misplaced. The expert in that case had, as plaintiffs point out, authored the regulation at issue, but he also had "over a decade" of experience with the implementation of the regulation. *Id.* at *2. The court found that the expert possessed "sufficient exposure to *and implementation of* the specific … regulations…." *Id.* (emphasis added). Trautman has no such experience and is not qualified to offer the opinions she presents in her reports.

III. CONCLUSION

For the foregoing reasons and those in Intuitive's opening brief, Intuitive's motion to exclude the opinions of Kimberly Trautman should be granted.

DATED: May 11, 2023

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